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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,580	04/24/2001	Andrea Califano	YOR920000687US2	5406
48062 7590 01/19/2007 RYAN, MASON & LEWIS, LLP 1300 POST ROAD SUITE 205 FAIRFIELD, CT 06824			EXAMINER CLOW, LORI A	
			ART UNIT	PAPER NUMBER
			1631	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/19/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/841,580	<b>Applicant(s)</b> CALIFANO ET AL.	
	<b>Examiner</b> Lori A. Clow, Ph.D.	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 17-19, 23-25 and 29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 17-19, 23-25, and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Applicants' response, filed 16 October 2006, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-3, 17-19, 23-25, and 29 are currently pending. Claims 4-16, 20-22, and 26-28 have been cancelled.

#### **Claim Rejections - 35 USC § 101**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 17-19, 23-25, and 29 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, for the reasons set forth in the previous Office Action. This rejection is newly applied to claims 17-19 and 23-25 based upon the current interpretation of the New Interim Guidelines for Examination of Patent Application for Patent Subject Matter Eligibility (MPEP 2106).

Claims 17-19 and 23-25 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. A statutory process must include a step of a physical transformation of matter, or produce a concrete, tangible, and useful result [State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998)], [AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999))].

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Claims 17-19 are directed to a system comprising a memory, a processor coupled to a memory, and computer-readable code configured to determine gene expression signals, transform gene expression signals, and characterize gene expression. Claims 23-25 are directed to an article of manufacture with a computer readable medium for the same steps. While the system comprises a memory and there is a physical medium, as in the computer-readable medium, the claim must accomplish a practical application. In the instant case the execution of instructions, for instance, does not accomplish a practical application (i.e. results in a *physical* transformation or produces a concrete, tangible, and useful *result*) and therefore, the claims are non-statutory.

This rejection could be overcome by amending the claims to recite that a result of the method is “displayed” or “outputted” (e.g. output to a user, a display, a memory, or another computer, etc.), or by amending the claims to include a step of a physical transformation of matter (e.g. assay). For an updated discussion of statutory considerations with regard to non-functional descriptive material and computer-related inventions, see the Guidelines for Patent Eligible Subject Matter in the MPEP 2106, Section IV.

#### **Response to Applicant’s Arguments Regarding 35 USC 101, Non-Statutory Subject Matter**

1. Applicant argues “for a subject matter to be statutory, the claimed process must be limited to a practical application of the abstract idea or mathematical algorithm in the technological arts”. Applicant further states that “a claim is limited to a practical application when the method, as claimed, produces a concrete, tangible, and useful result, i.e., the method recites a step or act of producing something that is concrete, tangible, and useful”. Applicants

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submit that the amended claims are limited to a practical application because they produce a concrete, tangible, and useful result of characterizing gene expression of an unknown sample by comparing gene expression of the unknown sample with gene expression patterns also produced by the claimed invention.

This is not found persuasive. The Examiner maintains that the instant claims are now drawn to a method for characterizing gene expression by determining expression signals, transforming the signals to get patterns, and characterizing gene expression based upon the expression patterns. As was set forth previously, the test for practical application is two-fold. No longer is practical application in the technological arts the standard to evaluate statutory subject matter. Rather, practical application refers to a claimed invention that “**transforms**” an article or physical object to a different state or thing OR a claimed invention that provides a practical application that produces a concrete, tangible, and useful result, based upon the factors recited in the previous Office Action. In the instant case, no transformation to a different state or thing is present. Therefore, the claims are evaluated for a practical application that provides a concrete, tangible, and useful result.

In the instant case, claims 1-3 and 29 do not recite a tangible result such that the result is useful to one skilled in the art. Rather, the instant claims could merely encompass *in silico* data manipulation with no specific output, such as output to a user. The tangible requirement does require that the claim must recite more than a 101 judicial exception, in that the process claim must set forth a practical application of that 101 judicial exception to produce a real-world result. Benson, 409 U.S. at 71-72, 175 USPQ at 676-77 (invention ineligible because no “substantial practical application.”). In the instant case, no real-world result is set forth.

**Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 17-19, 23-25, and 29 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

**Response to Applicant's Arguments Regarding 35 USC 112, Lack of Enablement**

1. Applicant argues that the amendments to claims 1-3, 17-19, and 23-25 overcome the rejections set forth in the previous Office Action.

This is not persuasive. It is maintained that the claims are not commensurate in scope with the specification and that the transformation of expression data is not enabled to perform the method steps as **instantly claimed**.

The specification fails to teach how to use transformed gene expression signals to determine gene expression patterns. The instantly amended claims are further drawn to characterizing gene expression of an unknown sample by comparing gene expression of an unknown sample with gene expression patterns. The specification fails to teach how to correlate gene expression of an unknown sample with gene expression patterns. The specification teaches the development of a "control matrix" (page 12) from which expression is determined by

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converting fluorescence to mathematical expressions which can be compared. Such is not represented in the instant claims. Further, the specification teaches expression data derived from healthy and unhealthy assays to develop an expression pattern representing phenotype sets (pages 18-20). Unknown samples are valuated to establish gene expression patterns which can then be compared to the phenotype sets in order to classify the unknown as belonging to a particular phenotype set. Such is not reflected in the instant claims. The claims remain rejected for lacking enablement.

No claims are allowed.

### **Inquiries**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also

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enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

January 13, 2007

Lori A. Clow, Ph.D.

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*Lori A. Clow*

*Patent Examiner*